555 Eleventh Street, N.W., Suite 1000
Washington, D.C. 20004-1304
Tel: +1.202.637.2200 Fax: +1.202.637.2201
www.lw.com

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March 6, 2009

VIA ELECTRONIC FILING

Ms. Marlene H. Dortch
Secretary
Federal Communications Commission
445 12th Street, S.W.
Washington, D.C. 20554

Re: Boston Scientific Corporation Request for Extension of Waiver
Respironics, Inc. and Boston Scientific Corporation, Requests for Waiver of Section 15.205 of the Commission's Rules to Permit the Marketing and Operation of Certain Medical Communications Devices that Operate in the 90-110 kHz Band, ET Docket No. 05-331

Dear Ms. Dortch:

Enclosed is a request for extension of a waiver granted to Boston Scientific Corporation ("Boston Scientific") in the above-referenced proceeding. Specifically, Boston Scientific seeks an extension of the November 16, 2009 expiration of the waiver permitting operation in the restricted 90-110 kHz band for its Contak Renewal TR device until the earlier of (i) May 8, 2011, or (ii) 90 days after the date on which the FDA approves the next-generation replacement for Contak Renewal TR. The company needs the certainty of a decision on this request in order to plan its business. Therefore, Boston Scientific respectfully requests that the Commission act promptly on this request for extension, and in no event later than June 30, 2009.

Respectfully submitted,

/s/

Teresa D. Baer
Elizabeth R. Park

Enclosure

cc: Bruce Romano

Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20554

In the Matter of	)	
	)	
Respironics, Inc. and Boston Scientific Corporation	)	
	)	
Requests for Waiver of Section 15.205 of the Commission's Rules to Permit the Marketing and Operation of Certain Medical Communications Devices that Operate in the 90-110 kHz Band	)	ET Docket No. 05-331

REQUEST FOR EXTENSION OF WAIVER

Boston Scientific Corporation ("Boston Scientific") hereby requests an extension of the waiver of Section 15.205(a) of the Commission's rules, granted in the above-referenced proceeding, permitting limited operations in the restricted 90-110 kHz band.[1] Specifically, Boston Scientific seeks an extension of the November 16, 2009 expiration of the waiver as it applies to Boston Scientific's Contak Renewal TR devices until the earlier of (i) May 8, 2011,[2] or (ii) 90 days after the date on which the FDA approves the next-generation replacement for Contak Renewal TR.[3] As described in more detail below, there is good cause for granting this extension request. The extension would ensure that the life-enhancing treatment option offered

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1 *Respironics, Inc. and Boston Scientific Corporation, Requests for Waiver of Section 15.205 of the Commission's Rules to Permit the Marketing and Operation of Certain Medical Communications Devices that Operate in the 90-110 kHz Band*, Order, 21 FCC Rcd 13450 (2006) ("Waiver Order").

2 The May 8, 2011 date would align the expiration of the Contak Renewal TR waiver with the expiration of the existing FCC waiver for the Cognis and Teligen devices.

3 The Contak Renewal TR devices distributed under this extension would represent less than 1% of the current population of Boston Scientific's implanted devices.

by the Contak Renewal TR product continues to be available to the public until an FCC-compliant replacement product, the Cognis CRT-P, can be brought to market.[4] Moreover, the limited extension that Boston Scientific seeks here would have at most a negligible interference potential to the primary users of the 90-110 kHz band.

I. Background

Boston Scientific is a leading worldwide manufacturer of implantable cardiac devices, such as pacemakers (or pacers), defibrillators and cardiac resynchronization therapy ("CRT") devices. These devices are implanted into patients with cardiovascular disease and deliver electrical stimuli to treat abnormal heart rhythms. The devices affected by the Waiver Order include the "Teligen," "Cognis," and "Contak Renewal TR" devices. The Teligen device is an implantable cardioverter defibrillator ("ICD"), which is designed to deliver a high voltage electrical impulse to treat a heart rhythm that is abnormally fast. The "Cognis" and "Contak Renewal TR" products are CRT devices. CRT devices resynchronize heart rhythms in patients suffering from heart failure. Most CRT devices also include a defibrillation capability and thus include high voltage electronics, most notably high voltage capacitors.[5] The Contak Renewal TR, however, is a unique, smaller[6] CRT device that does not deliver defibrillation therapy.[7]

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4 Boston Scientific is concurrently developing two versions of products on its Ingenio technology platform: a pacer (also known as a "pacemaker"), which delivers a low-energy pacing pulse to treat heart rhythms that are abnormally slow, and a CRT-P version that will be known as Cognis CRT-P. The Cognis CRT-P device offers resynchronization pacing therapy for the treatment of patients with heart failure, and will replace the Contak Renewal TR product.

5 The Cognis device that is covered by the FCC waiver includes defibrillation capability, so it is known as a "CRT-D" device.

6 Contak Renewal TR device lacks high voltage circuitry, such as high-voltage capacitors, and is thus significantly smaller than the defibrillation-capable version.

7 Physicians follow the approved indications for each type of therapy as defined by the American Heart Association/Heart Rhythm Society guidelines. Each patient's unique

Each of these implantable devices uses inductive telemetry to communicate with heart monitoring equipment, allowing physicians to download information stored in the device's memory to monitor a patient's cardiac events and the functioning of the implanted system.[8] Inductive telemetry operates using magnetic coupling between a coil in a hand-held "wand," and a coil in the implanted device. In the typical case, the physician initiates a communication session with the implanted device by placing the wand on the patient's chest over the device to establish an inductive link between the wand and the implanted device. The wand must be within centimeters of the device to detect the extremely low-power inductive transmissions.

Certain devices manufactured and distributed by Boston Scientific use an inductive telemetry system that emits extremely low levels of radio frequency ("RF") emissions in the 90-110 kHz band during communication periods. These frequencies are restricted under the Commission's rules to the Radionavigation Service ("LORAN-C") for Federal and non-Federal users.[9] Accordingly, on June 6, 2006, Boston Scientific requested a waiver of the Commission's rules to permit continued operation of its legacy devices (including the Contak Renewal TR), as well as the manufacture and distribution of certain "next-generation" devices that were then in development. At the time Boston Scientific filed the June 6, 2006 waiver request, the Cognis CRT device, Teligen ICD and Ingenio pacer were about six years into a development cycle, but were designed to use the 90-110 kHz band to initiate a communication session and as a backup means of data communication.

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condition is reviewed by a physician. Sometimes the patient and physician choose an implantable cardiac device that does not have defibrillation shock capabilities.

8 The implanted system includes an implantable device, such as Contak Renewal TR, and one or more leads (wires) that extend into or around the heart.

9 47 C.F.R. § 2.106. The term LORAN refers to Long Range Aids to Navigation.

On November 16, 2006, the Commission issued the Waiver Order, granting Boston Scientific a waiver to permit the manufacture and sale of (i) Contak Renewal TR devices until the earlier of (x) three years from the release date of the Waiver Order, or (y) six months after the final regulatory approval of its next-generation replacement devices, and (ii) Cognis, Teligen and Ingenio devices for three years after the release date of the Waiver Order (*i.e.*, until November 16, 2009).[10] The Commission determined that the short-term shortage that would result from requiring Boston Scientific to discontinue immediately the cardiac devices at issue would be detrimental to the public, particularly to cardiac patients.[11] The Commission further concluded that the likelihood that these products would interfere with LORAN-C operations in the 90-110 kHz band was negligible.[12]

At the time the Commission granted the waiver with respect to the Cognis and Teligen products, these products were still in development and were not expected to receive FDA approval until 2008, which would have been well into the waiver period. On December 18, 2006, Boston Scientific therefore requested a modification of the start date of the waiver period for the Cognis and Teligen devices to allow it sufficient time to bring these products to market and to sell them until FCC-compliant replacement products could be developed and introduced.[13]

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10 Waiver Order ¶ 13. The Waiver Order also permitted the manufacture and sale of certain other implantable pacemakers and cardioverter defibrillators (known as "PDM" and "PD2"). The waiver periods for those devices have since expired, and Boston Scientific has ceased marketing those products.

11 *Id.* ¶ 11.

12 *Id.*

13 Boston Scientific did not seek a modification of the waiver period for the Ingenio product platform, however, as the company had begun to redesign the product to emit outside of the 90-110 kHz band. At the time it sought the waiver modification, Boston Scientific expected to be able to complete its redesign of the Ingenio platform (including Cognis CRT-P) and be in a position to begin to market the new device before the end of the original waiver period for the Contak Renewal TR device. *See Respironics, Inc. and*

On July 11, 2007, the Commission modified the waiver to begin the three-year term for the Cognis and Teligen devices on the earlier of the date of FDA approval for the first device in the series, or January 31, 2009.[14] Boston Scientific received FDA approval on May 8, 2008, and thus the waiver for the Cognis and Teligen devices expires on May 8, 2011.

II. The Need for an Extension of the Waiver for the Contak Renewal TR Product

Although Boston Scientific has been working to finish and launch the Cognis CRT-P product, Boston Scientific will be unable to introduce the product before the November 16, 2009 expiration of the waiver for the Contak Renewal TR device. While, as originally designed, the Cognis CRT-P product would have used inductive coupling in the 90-110 kHz band for extremely short periods of time, Boston Scientific has been working to redesign Cognis CRT-P so that it uses inductive telemetry emitting on frequencies outside of the 90-110 kHz band, thus complying with the Commission's rules. However, despite its huge investment in quality and research and development,[15] and due to delays in the product development process, this redesign has taken longer than Boston Scientific initially anticipated.[16]

The Cognis CRT-P product is currently in the final stages of design development. In general, the extreme complexity and criticality of implantable cardiac devices necessitates a

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Boston Scientific Corporation, Requests for Waiver of Section 15.205 of the Commission's Rules to Permit the marketing and operation of certain medical communications devices that operate in the 90-110 kHz Band, Order, 22 FCC Rcd 12881 ¶ 5 n.4 (2007) ("Waiver Modification Order").

14 *Id.* ¶ 14.

15 Boston Scientific reinvested the highest percentage of sales revenue into R&D among publicly traded manufacturers of CRM devices for 2007.

16 In addition to the inductive telemetry redesign, Boston Scientific also recently reengineered how it designs, builds, tests, and reports on its cardiac rhythm management products. As part of that effort, the cardiac rhythm management division of Boston Scientific recently invested over $200 million and dedicated over 600 engineers to enhancing quality and reliability systems. These investments in quality and reliability have led to delays in several development projects, including the Cognis CRT-P device.

relatively long product development cycle and extensive post-development quality and reliability testing. In the case of the Cognis CRT-P product, the development period was lengthened further by the design changes and system testing required for an inductive telemetry subsystem emitting on frequencies outside of the 90-110 kHz band. This and other complexities arising in the development stage have necessarily significantly delayed the conclusion of the development phase of the Cognis CRT-P project and commencement of the reliability test phase.[17] Once the design development is complete, Boston Scientific will commence the reliability test cycle, which typically lasts approximately six months.

After completion of testing to verify design reliability, the FDA also must review and approve the device. FDA approval typically requires at least six months.[18] Based on this schedule, Boston Scientific currently expects to receive FDA approval for the Cognis CRT-P product, and be in a position to commence manufacturing and distributing the new devices, by or before May 2011.

Accordingly, Boston Scientific requests an extension of the waiver period for the Contak Renewal TR device, to provide a "bridge" to the FCC-compliant replacement product. Specifically, Boston Scientific requests an extension of the waiver to allow Boston Scientific to manufacture and distribute Contak Renewal TR devices until the earlier of (i) May 8, 2011 (the expiration date of the modified Cognis and Teligen waivers), or (ii) 90 days[19] after the date on

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17 Due to the critical functions performed by implantable cardiac devices, Boston Scientific requires all of its implantable cardiac device products to meet extraordinary quality and reliability standards.

18 If compilation and review of additional clinical data is needed, FDA review and approval could take substantially longer than six months.

19 This 90 day period after FDA approval is needed as a practical matter to provide time to stop distribution of the current product and begin manufacturing and distributing the compliant replacement product. More specifically, after FDA approval of the

which the FDA approves the Cognis CRT-P version of the Ingenio device.[20] In other words, Boston Scientific requests a waiver extension of slightly less than 18 months, and less if FDA approval is received sooner.

III. The Circumstances in This Case Justify an Extension of the Waiver

There is good cause for extending the Contak Renewal TR waiver here.[21] A limited extension of the waiver for the Contak Renewal TR device is justified by the life-enhancing benefits that the device offers with virtually no risk of harmful interference to LORAN-C users. This extension request is limited to the length of time required to complete development and testing, and obtain FDA approval. Once the replacement product can be brought to market, cardiac patients and physicians will have access to the CRT therapy in a pacer-sized device that does not emit in the restricted band.

In the November 16, 2006 Waiver Order, the Commission recognized the importance of Boston Scientific's cardiac devices to heart patients and noted that restricting the

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replacement product, Boston Scientific needs a period of time to get sales contracts in place with hospitals and other patient care providers to avoid a disruption in availability of devices for patients. Boston Scientific is thus requesting a 90-day transition period to phase-out the Contak Renewal TR and phase-in the replacement product. While the original waiver order allowed six months to phase out Contak Renewal TR after FDA approval of a replacement product, Boston Scientific is requesting only 90 days to minimize its presence in the restricted band.

20 Boston Scientific would agree to notify the Commission in writing within ten business days of its submission of the Cognis CRT-P to the FDA for approval, *see, e.g.,* Waiver Modification Order ¶ 14, and/or of receipt of FDA approval.

21 *See* 47 C.F.R. § 1.3 ("Any provision of the rules may be waived by the Commission . . . if good cause therefore is shown."). A waiver of the Commission's rules is appropriate where, as here, special circumstances warrant a deviation from the rule and strict compliance with the rule is inconsistent with the public interest. *WAIT Radio v. FCC*, 418 F.2d 1153, 1159 (D.C. Cir. 1969); *see also, Northeast Cellular Telephone Co. v. FCC*, 897 F.2d 1164, 1166 (D.C. Cir. 1990).

availability of these products would be harmful to the public interest.[22] Even "the short-term product shortage that would result from taking the current devices off the market without a phase-out period would likely be detrimental to the public, and specifically medical patients and their families who benefit from their use."[23] That same reasoning supports a grant of this Contak Renewal TR extension request. Without an extension, there would be a gap of up to 18 months during which cardiac patients would not have access to any Boston Scientific CRT-P device with the unique pacer/cardiac resynchronization functionality offered in the Contak Renewal TR product. Until the Cognis CRT-P becomes available, the Contak Renewal TR is the only CRT product offered by Boston Scientific with this functionality.

Moreover, the Commission acknowledged in the Waiver Order that the risk of interference with LORAN-C operations in the restricted 90-110 kHz is negligible.[24] Indeed, there have been no reported cases and no complaints of interference. LORAN-C users include the U.S. Coast Guard and non-federal aviation and Private Land Mobile services, and thus, LORAN-C receivers typically operate on mobile air, land and marine platforms. It is extremely unlikely that a cardiac device communicating in the restricted band with nearby external clinical equipment would interfere with any LORAN-C communications. Cardiac devices generate RF energy in the 90-110 kHz band at extremely low levels and for periods of only a few minutes over the course of a year.[25] The extremely low level inductive signals generated by cardiac devices are so weak that the specially-designed monitoring device can pick up the inductive

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22 Waiver Order ¶ 11.

23 *Id.*

24 *Id.* For avoidance of doubt, only the emissions from the implanted device conflict with the restricted band rules. The external programming and monitoring equipment transmits on a frequency outside the restricted band and is compliant with FCC rules.

25 Typically, the Contak Renewal TR inductive system is operated for about twenty minutes about four times per year in a clinical setting.

signals only if the wand is in very close proximity to the device – just a few centimeters from the patient's body. Moreover, the inductive communication function in the Contak Renewal TR device is operated only in controlled environments, such as a hospital or doctor's office. Given the operational parameters and the location of use of the devices while transmitting in the restricted band, the risk of harmful interference to LORAN-C users is virtually nonexistent.

This request does not significantly increase the risk of interference because the duration of the requested extension would not exceed the timeframe for the existing waiver for the Cognis and Teligen products. Furthermore, the Cognis CRT-P is a relatively low-volume product. Based on Boston Scientific's projected requirements of patient needs for a CRT-P device, the number of Contak Renewal TR devices that would likely be distributed during the period of the requested extension represents less than one percent of Boston Scientific's cardiac devices currently in use. Thus, granting the brief extension requested would not materially alter the negligible interference risk to LORAN-C users.

IV. Conclusion

For the foregoing reasons, Boston Scientific respectfully requests that the Commission grant an extension of the waiver for the Contak Renewal TR device until the earlier of (i) May 8, 2011, or (ii) 90 days after the date on which the FDA approves the Cognis CRT-P.

Respectfully submitted,

/s/

Teresa D. Baer
Elizabeth R. Park
LATHAM & WATKINS LLP
555 Eleventh Street, N.W.
Suite 1000
Washington, D.C. 20004
(202) 637-2200

Counsel for Boston Scientific Corporation

March 6, 2009